

REMARKS

Claims 1-5, 8, 9, and 12-21 are currently pending in the application. Only claims 1 and 12 are in independent form.

Claims 12, 14-18, and 20-21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Behnke et al. patent. Reconsideration of the rejection is respectfully requested.

The Office Action states that the Behnke et al. patent teaches a dipstick immunodisplacement device and method wherein an analyte in a sample displaces bound label from a specific binder bound to a solid phase, which is dipped into the vessel containing the sample. However, when read more specifically, the Behnke et al. patent discloses a much more complicated process. As set forth in column 5, lines 20-33, the process involves taking a test solution that contains a sample and another reaction partner and contacts the solution with one end of a test strip. The test solution is allowed to pass over at least one part of the test strip, including the partial area containing the antibody, by capillary migration. The test strip is subsequently washed and brought into contact with a developing solution that contains members of a signal-generating system that are able to generate a detectable signal as a function of the amount of analyte in the sample and the partial area containing the antibody. This is in contradistinction with the method of the presently pending claims, which instead does not require a washing step.

It was previously thought by those of skill in the art that a washing step was required in order to stop the reaction; i.e., stopping the biological activity of the bioactive molecule and also to remove any unbound ligand. The presently claimed invention is beneficial over the prior art in that the washing step is no longer required and is excluded, simplifying the assaying procedure. More specifically, the prior art requires a washing step. In contradistinction, the presently amended independent claims include closed language that excludes a washing step, as suggested in the outstanding Office Action. The independent

claims have been amended to recite closed language that does not include a washing step, as is required by the Behnke, et al. patent. Since the Behnke et al. patent does not disclose the method of the presently pending claims, the claims are patentable over the Behnke et al. patent and reconsideration of the rejection is respectfully requested.

Reconsideration of the rejection under 35 U.S.C. §103 over Marquardt et al., Eibl et al., Fish et al. and Kohler et al. in view of Marquardt et al., Eibl et al., Fish et al. and Kohler et al. as applied to the present claims is respectfully requested.

The Office Action states that the Marquardt et al. patent teaches solid phase assays, both competitive and non-competitive, for bioactive substances, including enzymes and their inhibitors, essentially as instantly disclosed except for being performed in microtiter plates rather than on an insertable solid phase. However, as set forth in the present specification on page 2, lines 24-30, the method of the Marquardt et al. patent involves multiple steps including coating the wells of the microplate, washing the wells, adding biologically active substance to the wells, washing the wells once more, adding the indicator's enzyme to the wells, washing the wells again, and adding a colored development reagent. Therefore, this assay cannot be readily used in assays requiring rapid analysis and the method involves a multitude of steps as compared to the presently pending claims. Further, the Marquardt et al. patent requires a washing and development step. It is previously known to those of skill in the art that washing was required in order to stop the reaction; i.e., stopping the biological activity of the bioactive molecule and also to remove any unbound ligand. The presently pending claims are an improvement over the prior art in that they are able to remove the washing step and thereby simplify the assaying procedures. Therefore, the Marquardt et al. patent does not disclose or suggest the method of the presently pending claims.

The Office Action states that the Eibl et al. patent discloses elongated elements such as "platelets" or pins, which are secured to a holding band in a

carrier and that are insertable into the recesses of a microtiter plate containing samples to be assayed. Further, the Office Action states that various competitive assay formats are taught using an antigen or antibody bound to the elements and a labeled antigen or antibody added to the sample. The Office Action concludes that the Eibl et al. patent teaches the carrier for the avoidance of complicated separating and washing procedures as are found in prior art assays performed with coated vessels, such as tubes.

It is undisputed that the Eibl et al. patent discloses an assay kit that requires a washing step in order to measure the radioactivity of the carrier. While the Eibl et al. patent discloses an assay kit with a decreased amount of steps required for performing the assay, it still requires washing procedures to be used in order for the assay to perform properly. This is in contradistinction with the method of the presently pending claims, which instead do not require a washing step. It was previously thought by those of skill in the art that washing was required in order to stop the reaction; i.e., stopping the biological activity of the bioactive molecule and also to remove any unbound ligand. The presently pending claims have been amended to include closed language and exclude a washing step. Since the Eibl et al. patent requires a washing step, the Eibl et al. patent does not disclose or suggest the method of the presently pending claims.

The Fish et al. patent, according to the Office Action, teaches the general use of coated comb-like carriers for assays to detect binding of a variety of receptor-analyte pairs, such as enzyme-substrate, antibody-antigen, antigen-antibody, receptor-toxin, receptor-drug, or complementary nucleic acid pairs. However, when read more specifically, the Fish et al. patent again requires a washing step as found in the above described prior art patents. Specifically, the card of the Fish et al. patent must be developed in order to determine the presence of an analyte in each of the samples. The card is washed and then immersed in a second compartment and any additional compartments. This developing step is not required by the present invention nor do the presently pending claims recite use of a card for conducting the assay. Therefore, the

Fish et al. patent does not disclose or suggest the method of the presently pending claims.

Finally, the Office Action states that the Köhler patent teaches a comb-like carrier coated with antigens or antibodies for immunological assays as an alternative to coated microtiter plates, using a microtiter plate only as a vessel for multiple samples. However, the Köhler patent discloses in column 2, line 67 through column 3, line 6, that the strips are treated with a reagent in conjunction with naphthol, which is subject to a color change as a result of the immunological reactions. The reaction result cannot otherwise be observed optically. Therefore, as with the above referenced prior art patents, there is a requirement that an additional washing or treatment step be performed in order for the assay to function properly. This is in contradistinction with the assay and method of the presently pending claims, which instead require that no washing step be used. Therefore, the Köhler patent does not disclose or suggest the assay and method of the presently pending claims.

Claims 1-5, 8, 9, and 12-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Piasio et al. patent in view of the Ryan et al. patent. Reconsideration of the rejection is respectfully requested.

The Office Action states that the Piasio et al. patent teaches a method and apparatus for conducting a chemical enzymatic or immunochemical reaction wherein one or more of the reactants are fixed to the surface of an immersible solid phase matrix and one or more reactants are freely diffusible in a liquid reaction medium in which the solid phase matrix is immersed. However, when read more specifically, the Piasio et al. patent discloses a matrix that is utilized to test for the presence of a specific compound in a solution. The matrix itself is the important functional aspect of the invention. The patent discloses that the matrix enables the reaction rate to be controlled such that the reaction can approach equilibrium, which is desired. There is disclosed in the Piasio et al. patent that equilibrium can be difficult to obtain and often there are errors in starting and stopping the reaction, by utilizing the matrix of the Piasio et al. patent an

individual can easily and quickly reach the equilibrium, stop the reaction, and thereby control the rate of the reaction more specifically. Additionally, the matrix is designed to include a specific reaction component and is not designed to measure any unknown component as can be assayed by the assay of the presently pending independent claims. The Piasio et al. patent states at column 11, lines 56-60 that the immobilized reaction should be bound to the matrix with sufficient strength such that a non-appreciable amount of reactant becomes desorbed or otherwise removed during the incubations and washing steps of the reaction. It is critical that washing steps be utilized in conjunction with the assay of the Piasio et al. patent. No such steps are required by the presently pending independent claims. Further, the presently pending claims do not utilize a matrix for reaching equilibrium but instead utilize the assay to quantitate an amount of a desired substrate in a solution. For example, the method of the presently pending independent claims enables the reaction to begin when the probe is inserted into the sample and the removal of the probe into the reaction vessel ends the reaction. There is no requirement that an equilibrium be reached nor is there a requirement that the probe include a matrix that includes a large amount of surface as required by the Piasio et al. patent. These requirements are excluded by the claims as pending. Therefore, the Piasio et al. patent neither discloses nor suggests the assay of the presently pending independent claims.

The Office Action states that the Ryan et al. patent teaches radiolabeled substrates for assays of angiotensin converting enzyme (ACE) in samples of biological material with or without the addition of enzyme inhibitors to the samples. There is no disclosure in the Ryan et al. patent for stopping the reaction simply by removing a probe from the reaction vessel as recited in the presently pending independent claims. Instead the reaction is stopped by the addition by the suitable inhibitor and the reaction mixture is extracted with a measured volume of organic solvent. An aliquot of the solvent that contains any radioactive remnant reaction product by the action of the enzyme it is transferred to another vial for measurement of radioactivity as specifically disclosed at

column 4, lines 5-13. Therefore the Ryan et al. patent does not teach or suggest the method of the presently pending independent claims.

The Office Action concludes that it would be obvious to use labeled enzyme substrate affixed to the solid phases for assays of enzymatic activity and biological samples using the labeled substrates of the Ryan et al. patent with the apparatus and method of the Piasio et al. patent. However, the Piasio et al. patent requires that the solid phase include a matrix. There is no disclosure in the presently pending claims of the benefits of the use of a matrix and as the claims contain closed language the matrix is excluded from the scope of the presently pending independent claims. Accordingly, reconsideration of the rejection is respectfully requested.

Claims 1-5, 8, 9, and 12-21, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Marquardt et al. patent, Piasio et al. patent, and Ryan et al patent. Reconsideration of the rejection is respectfully requested.

As set forth above, neither the Marquardt et al. patent, Piasio et al. patent, or Ryan et al. patent, alone or in combination, teach or suggest the method of the presently pending independent claims. Accordingly, the claims are patentable over the cited prior art and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In conclusion, the present application is in condition for allowance, which allowance is respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

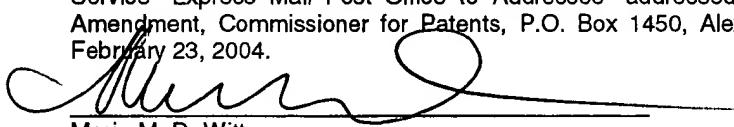

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